106TH CONGRESS
1ST SESSION

S. 6

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE SENATE OF THE UNITED STATES

JANUARY 19, 1999

Mr. DASCHLE (for himself, Mr. KENNEDY, Mrs. BOXER, Mr. DODD, Mr. DORGAN, Mr. EDWARDS, Mr. CLELAND, Mr. REID, Mr. DURBIN, Mrs. MURRAY, Mr. AKAKA, Mr. WYDEN, Mr. HARKIN, Ms. MIKULSKI, Mr. LEAHY, Mr. REED, Mr. SARBANES, Mr. WELLSTONE, Mrs. FEINSTEIN, Mr. BYRD, Mr. ROCKEFELLER, Mr. KERRY, Mr. TORRICELLI, Mr. BINGAMAN, Mr. BRYAN, Mr. JOHNSON, Mr. LAUTENBERG, Mr. SCHUMER, and Mr. INOUYE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patients' Bill of Rights Act of 1999".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—HEALTH INSURANCE BILL OF RIGHTS

Subtitle A—Access to Care

SEC. 101. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to emergency services (as defined in paragraph (2)(B)), the plan or issuer shall cover emergency services furnished under the plan or coverage—

(A) without the need for any prior authorization determination;

(B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating health care provider without prior authorization by the plan or issuer, the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization by the plan or issuer; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—

The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term "emergency services" means—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)), and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment

as are required under section 1867 of such Act to stabilize the patient.

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—In the case of services (other than emergency services) for which benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with the guidelines established under section 1852(d)(2) of the Social Security Act (relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after an enrollee has been determined to be stable), or, in the absence of guidelines under such section, such guidelines as the Secretary shall establish to carry out this subsection), if the services are maintenance care or post-stabilization care covered under such guidelines.

SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS UNDER GROUP HEALTH PLANS.

(a) REQUIREMENT.—

(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (or health insurance coverage offered by a health insurance issuer in connection with a group health plan) provides benefits only through participating health care providers, the plan or issuer shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan or coverage and at such other times as the plan or issuer offers the participant a choice of coverage options.

(2) EXCEPTION.—Paragraph (1) shall not apply with respect to a participant in a group health plan if the plan offers the participant a choice of health insurance coverage.

(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term ''point-of-service coverage'' means, with respect to benefits covered under a group health plan or health insurance issuer, coverage of such benefits when provided by a nonparticipating health care provider. Such coverage need not include coverage of providers that the

plan or issuer excludes because of fraud, quality, or similar reasons.

(c) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring coverage for benefits for a particular type of health care provider;

(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options; or

(3) as preventing a group health plan or health insurance issuer from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option.

(d) NO REQUIREMENT FOR GUARANTEED AVAILABILITY.—If a health insurance issuer offers health insurance coverage that includes point-of-service coverage with respect to an employer solely in order to meet the requirement of subsection (a), nothing in section 2711(a)(1)(A) of the Public Health Service Act shall be construed as requiring the offering of such coverage with respect to another employer.

SEC. 103. CHOICE OF PROVIDERS.

(a) PRIMARY CARE.—A group health plan, and a health insurance issuer that offers health insurance cov-

erage, shall permit each participant, beneficiary, and enrollee to receive primary care from any participating primary care provider who is available to accept such individual.

(b) SPECIALISTS.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.

(2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating providers with respect to such care.

SEC. 104. ACCESS TO SPECIALTY CARE.

(a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

(1) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider—

(A) the plan or issuer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider; and

(B) if such an individual has not designated such a provider as a primary care provider, the plan or issuer—

(i) may not require authorization or a referral by the individual's primary care provider or otherwise for coverage of routine gynecological care (such as preventive women's health examinations) and pregnancy-related services provided by a participating health care professional who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and

(ii) may treat the ordering of other gynecological care by such a participating health professional as the authorization of the primary care provider with respect to such care under the plan or coverage.

(2) CONSTRUCTION.—Nothing in paragraph (1)(B)(ii) shall waive any requirements of coverage

relating to medical necessity or appropriateness with respect to coverage of gynecological care so ordered.

(b) PEDIATRIC CARE.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider for a child of such participant, beneficiary, or enrollee, the plan or issuer shall permit the participant, beneficiary, or enrollee to designate a physician who specializes in pediatrics as the child's primary care provider.

(c) SPECIALTY CARE.—

(1) SPECIALTY CARE FOR COVERED SERVICES.—

(A) IN GENERAL.—If—

(i) an individual is a participant or beneficiary under a group health plan or an enrollee who is covered under health insurance coverage offered by a health insurance issuer,

(ii) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, and

(iii) benefits for such treatment are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

(B) SPECIALIST DEFINED.—For purposes of this subsection, the term "specialist" means, with respect to a condition, a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

(C) CARE UNDER REFERRAL.—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under subparagraph (A) be—

(i) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the

individual (or the individual's designee), and

(ii) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(D) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under subparagraph (A) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

(E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan (if any)

shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(2) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

(A) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(B) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and

other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in paragraph (1)(C)(i)).

(C) ONGOING SPECIAL CONDITION DEFINED.—In this paragraph, the term "special condition" means a condition or disease that—

(i) is life-threatening, degenerative, or disabling, and

(ii) requires specialized medical care over a prolonged period of time.

(D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

(3) STANDING REFERRALS.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing

care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

SEC. 105. CONTINUITY OF CARE.

(a) IN GENERAL.—

(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an in-

dividual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing a course of treatment from the provider at the time of such termination, the plan or issuer shall—

(A) notify the individual on a timely basis of such termination, and

(B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider during a transitional period (provided under subsection (b)).

(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) TERMINATION.—In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

(b) TRANSITIONAL PERIOD.—

(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

(2) INSTITUTIONAL CARE.—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

(3) PREGNANCY.—If—

(A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and

(B) the provider was treating the pregnancy before date of the termination,

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, and

(B) the provider was treating the terminal illness before the date of termination,

the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under

subsection (a)(1)(B) upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant

to a treatment plan (if any) approved by the plan or issuer.

(d) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term "qualified individual" means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term "approved clinical trial" means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are

that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

SEC. 107. ACCESS TO NEEDED PRESCRIPTION DRUGS.

(a) IN GENERAL.—If a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the plan or issuer shall—

(1) ensure participation of participating physicians and pharmacists in the development of the formulary;

(2) disclose to providers and, disclose upon request under section 121(c)(6) to participants, beneficiaries, and enrollees, the nature of the formulary restrictions; and

(3) consistent with the standards for a utilization review program under section 115, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

(b) COVERAGE OF APPROVED DRUGS AND MEDICAL DEVICES.—

(1) IN GENERAL.—A group health plan (or health insurance coverage offered in connection with such a plan) that provides any coverage of prescription drugs or medical devices shall not deny coverage of such a drug or device on the basis that the use is investigational, if the use—

(A) in the case of a prescription drug—

(i) is included in the labeling authorized by the application in effect for the drug pursuant to subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act, without regard to any postmarketing requirements that may apply under such Act; or

(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public Health Service Act, without regard to any

postmarketing requirements that may apply pursuant to such section; or

(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

(2) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any coverage of prescription drugs or medical devices.

SEC. 108. ADEQUACY OF PROVIDER NETWORK.

(a) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage, that provides benefits, in whole or in part, through participating health care providers shall have (in relation to the coverage) a sufficient number, distribution, and variety of qualified participating health care providers to ensure that all covered health care services, including specialty services, will be available and accessible in a timely manner to all participants, beneficiaries, and enrollees under the

plan or coverage. This subsection shall only apply to a plan's or issuer's application of restrictions on the participation of health care providers in a network and shall not be construed as requiring a plan or issuer to create or establish new health care providers in an area.

(b) TREATMENT OF CERTAIN PROVIDERS.—The qualified health care providers under subsection (a) may include Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers located in the service area of the plan or issuer and shall include such providers if necessary to meet the standards established to carry out such subsection.

SEC. 109. NONDISCRIMINATION IN DELIVERY OF SERVICES.

(a) APPLICATION TO DELIVERY OF SERVICES.—Subject to subsection (b), a group health plan, and health insurance issuer in relation to health insurance coverage, may not discriminate against a participant, beneficiary, or enrollee in the delivery of health care services consistent with the benefits covered under the plan or coverage or as required by law based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as relating to the eligibility to be covered,

or the offering (or guaranteeing the offer) of coverage, under a plan or health insurance coverage, the application of any pre-existing condition exclusion consistent with applicable law, or premiums charged under such plan or coverage. Pursuant to section 192(b), except as provided in section 152, nothing in this title shall be construed as requiring a group health plan or health insurance issuer to provide specific benefits under the terms of such plan or coverage.

Subtitle B—Quality Assurance

SEC. 111. INTERNAL QUALITY ASSURANCE PROGRAM.

(a) REQUIREMENT.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall establish and maintain an ongoing, internal quality assurance and continuous quality improvement program that meets the requirements of subsection (b).

(b) PROGRAM REQUIREMENTS.—The requirements of this subsection for a quality improvement program of a plan or issuer are as follows:

(1) ADMINISTRATION.—The plan or issuer has a separate identifiable unit with responsibility for administration of the program.

(2) WRITTEN PLAN.—The plan or issuer has a written plan for the program that is updated annually and that specifies at least the following:

(A) The activities to be conducted.

(B) The organizational structure.

(C) The duties of the medical director.

(D) Criteria and procedures for the assessment of quality.

(3) SYSTEMATIC REVIEW.—The program provides for systematic review of the type of health services provided, consistency of services provided with good medical practice, and patient outcomes.

(4) QUALITY CRITERIA.—The program—

(A) uses criteria that are based on performance and patient outcomes where feasible and appropriate;

(B) includes criteria that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate;

(C) includes methods for informing covered individuals of the benefit of preventive care and what specific benefits with respect to preventive care are covered under the plan or coverage; and

(D) makes available to the public a description of the criteria used under subparagraph (A).

(5) SYSTEM FOR REPORTING.—The program has procedures for reporting of possible quality concerns by providers and enrollees and for remedial actions to correct quality problems, including written procedures for responding to concerns and taking appropriate corrective action.

(6) DATA ANALYSIS.—The program provides, using data that include the data collected under section 112, for an analysis of the plan's or issuer's performance on quality measures.

(7) DRUG UTILIZATION REVIEW.—The program provides for a drug utilization review program in accordance with section 114.

(c) DEEMING.—For purposes of subsection (a), the requirements of—

(1) subsection (b) (other than paragraph (5)) are deemed to be met with respect to a health insurance issuer that is a qualified health maintenance organization (as defined in section 1310(c) of the Public Health Service Act); or

(2) subsection (b) are deemed to be met with respect to a health insurance issuer that is accred-

ited by a national accreditation organization that the Secretary certifies as applying, as a condition of certification, standards at least a stringent as those required for a quality improvement program under subsection (b).

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

SEC. 112. COLLECTION OF STANDARDIZED DATA.

(a) IN GENERAL.—A group health plan and a health insurance issuer that offers health insurance coverage shall collect uniform quality data that include a minimum uniform data set described in subsection (b).

(b) MINIMUM UNIFORM DATA SET.—The Secretary shall specify (and may from time to time update) the data required to be included in the minimum uniform data set under subsection (a) and the standard format for such data. Such data shall include at least—

(1) aggregate utilization data;

(2) data on the demographic characteristics of participants, beneficiaries, and enrollees;

(3) data on disease-specific and age-specific mortality rates and (to the extent feasible) morbidity rates of such individuals;

(4) data on satisfaction (including satisfaction with respect to services to children) of such individuals, including data on voluntary disenrollment and grievances; and

(5) data on quality indicators and health outcomes, including, to the extent feasible and appropriate, data on pediatric cases and on a gender-specific basis.

(c) AVAILABILITY.—A summary of the data collected under subsection (a) shall be disclosed under section 121(b)(9). The Secretary shall be provided access to all the data so collected.

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

(e) EXCEPTION FOR NON-MEDICAL, RELIGIOUS CARE PROVIDERS.—The requirements of subsection (a), insofar as they may apply to a provider of health care, do not apply to a provider that provides no medical care

and that provides only a religious method of healing or religious nonmedical nursing care.

SEC. 113. PROCESS FOR SELECTION OF PROVIDERS.

(a) IN GENERAL.—A group health plan and a health insurance issuer that offers health insurance coverage shall, if it provides benefits through participating health care professionals, have a written process for the selection of participating health care professionals, including minimum professional requirements.

(b) VERIFICATION OF BACKGROUND.—Such process shall include verification of a health care provider's license and a history of suspension or revocation.

(c) RESTRICTION.—Such process shall not use a high-risk patient base or location of a provider in an area with residents with poorer health status as a basis for excluding providers from participation.

(d) NONDISCRIMINATION BASED ON LICENSURE.—

(1) IN GENERAL.—Such process shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(2) CONSTRUCTION.—Paragraph (1) shall not be construed—

(A) as requiring the coverage under a plan or coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(B) to override any State licensure or scope-of-practice law.

(e) GENERAL NONDISCRIMINATION.—

(1) IN GENERAL.—Subject to paragraph (2), such process shall not discriminate with respect to selection of a health care professional to be a participating health care provider, or with respect to the terms and conditions of such participation, based on the professional's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act of 1990).

(2) RULES.—The appropriate Secretary may establish such definitions, rules, and exceptions as may be appropriate to carry out paragraph (1), taking into account comparable definitions, rules, and

exceptions in effect under employment-based nondiscrimination laws and regulations that relate to each of the particular bases for discrimination described in such paragraph.

SEC. 114. DRUG UTILIZATION PROGRAM.

A group health plan, and a health insurance issuer that provides health insurance coverage, that includes benefits for prescription drugs shall establish and maintain, as part of its internal quality assurance and continuous quality improvement program under section 111, a drug utilization program which—

(1) encourages appropriate use of prescription drugs by participants, beneficiaries, and enrollees and providers, and

(2) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions.

SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with

a utilization review program that meets the requirements of this section.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section 111(b)(4)(B).

(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term "health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and, to the extent required, who have received appropriate training in the conduct of such activities under the program.

(B) PEER REVIEW OF SAMPLE OF ADVERSE CLINICAL DETERMINATIONS.—Such a program shall provide that clinical peers (as defined in section 191(c)(2)) shall evaluate the clinical appropriateness of at least a sample of adverse clinical determinations.

(C) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

(i) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

(ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered.

(D) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(5) LIMITATION ON INFORMATION REQUESTS.—Under such a program, information shall be required

to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(2) CONTINUED CARE.—In the case of a utilization review activity involving authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, the utilization review program shall make a determination concerning such

authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination. Such notice shall include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date, if any.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination.

(4) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-

STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section 101, respectively.

(e) NOTICE OF ADVERSE DETERMINATIONS.—

(1) IN GENERAL.—Notice of an adverse determination under a utilization review program shall be provided in printed form and shall include—

(A) the reasons for the determination (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 132; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such determination.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the determination in order to make a decision on such an appeal.

SEC. 116. HEALTH CARE QUALITY ADVISORY BOARD.

(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.

(b) NUMBER AND APPOINTMENT.—The advisory board shall be composed of the Secretary of Health and Human Services (or the Secretary's designee), the Secretary of Labor (or the Secretary's designee), and 20 additional members appointed by the President, in consultation with the Majority and Minority Leaders of the Senate and House of Representatives. The members so appointed shall include individuals with expertise in—

(1) consumer needs;

(2) education and training of health professionals;

(3) health care services;

(4) health plan management;

(5) health care accreditation, quality assurance, improvement, measurement, and oversight;

(6) medical practice, including practicing physicians;

(7) prevention and public health; and

(8) public and private group purchasing for small and large employers or groups.

(c) DUTIES.—The advisory board shall—

(1) identify, update, and disseminate measures of health care quality for group health plans and health insurance issuers, including network and non-network plans;

(2) advise the Secretary on the development and maintenance of the minimum data set in section 112(b); and

(3) advise the Secretary on standardized formats for information on group health plans and health insurance coverage.

The measures identified under paragraph (1) may be used on a voluntary basis by such plans and issuers. In carrying out paragraph (1), the advisory board shall consult and cooperate with national health care standard setting bodies which define quality indicators, the Agency for Health Care Policy and Research, the Institute of Medicine, and other public and private entities that have expertise in health care quality.

(d) REPORT.—The advisory board shall provide an annual report to Congress and the President on the quality of the health care in the United States and national and regional trends in health care quality. Such report shall include a description of determinants of health care

quality and measurements of practice and quality variability within the United States.

(e) SECRETARIAL CONSULTATION.—In serving on the advisory board, the Secretaries of Health and Human Services and Labor (or their designees) shall consult with the Secretaries responsible for other Federal health insurance and health care programs.

(f) VACANCIES.—Any vacancy on the board shall be filled in such manner as the original appointment. Members of the board shall serve without compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the performance of their duties. Administrative support, scientific support, and technical assistance for the advisory board shall be provided by the Secretary of Health and Human Services.

(g) CONTINUATION.—Section 14(a)(2)(B) of the Federal Advisory Committee Act (5 U.S.C. App.; relating to the termination of advisory committees) shall not apply to the advisory board.

Subtitle C—Patient Information

SEC. 121. PATIENT INFORMATION.

(a) DISCLOSURE REQUIREMENT.—

(1) GROUP HEALTH PLANS.—A group health plan shall—

(A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) or (c) in printed form.

(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

(A) provide to individuals enrolled under such coverage at the time of enrollment, and at

least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to enrollees, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c) in printed form.

(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer includes the following:

(1) SERVICE AREA.—The service area of the plan or issuer.

(2) BENEFITS.—Benefits offered under the plan or coverage, including—

(A) covered benefits, including benefit limits and coverage exclusions;

(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any

liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by non participating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of providers under the plan or coverage.

(B) Out-of-network coverage (if any) provided by the plan or coverage.

(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

(D) The procedures for participants, beneficiaries, and enrollees to select, access, and

change participating primary and specialty providers.

(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 103(b)(2).

(H) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals and including the provision of information in a language other than English if 5 percent of the number of participants, beneficiaries, and enrollees communicate in that language instead of English.

(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.

(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(B) the process and procedures of the plan or issuer for obtaining emergency services; and

(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(6) PERCENTAGE OF PREMIUMS USED FOR BENEFITS (LOSS-RATIOS).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).

(7) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review require-

ments that could result in noncoverage or nonpayment.

(8) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.

(9) QUALITY ASSURANCE.—A summary description of the data on quality collected under section 112(a), including a summary description of the data on satisfaction of participants, beneficiaries, and enrollees (including data on individual voluntary disenrollment and grievances and appeals) described in section 112(b)(4).

(10) SUMMARY OF PROVIDER FINANCIAL INCENTIVES.—A summary description of the information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(11) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

(12) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section 115, including under any drug formulary program under section 107.

(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

(3) METHOD OF PHYSICIAN COMPENSATION.—An overall summary description as to the method of compensation of participating physicians, including information on the types of financial payment incen-

tives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(4) SPECIFIC INFORMATION ON CREDENTIALS OF PARTICIPATING PROVIDERS.—In the case of each participating provider, a description of the credentials of the provider.

(5) CONFIDENTIALITY POLICIES AND PROCEDURES.—A description of the policies and procedures established to carry out section 122.

(6) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

(7) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

(d) FORM OF DISCLOSURE.—

(1) UNIFORMITY.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with applicable State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area.

(2) INFORMATION INTO HANDBOOK.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from

making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.

(3) UPDATING PARTICIPATING PROVIDER INFORMATION.—The information on participating health care providers described in subsection (b)(3)(C) shall be updated within such reasonable period as determined appropriate by the Secretary. Nothing in this section shall prevent an issuer from changing or updating other information made available under this section.

(e) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

SEC. 122. PROTECTION OF PATIENT CONFIDENTIALITY.

Insofar as a group health plan, or a health insurance issuer that offers health insurance coverage, maintains medical records or other health information regarding participants, beneficiaries, and enrollees, the plan or issuer shall establish procedures—

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely, and

(3) to assure timely access of such individuals to such records and information.

SEC. 123. HEALTH INSURANCE OMBUDSMEN.

(a) IN GENERAL.—Each State that obtains a grant under subsection (c) shall provide for creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. Such Ombudsman shall be responsible for at least the following:

(1) To assist consumers in the State in choosing among health insurance coverage or among coverage options offered within group health plans.

(2) To provide counseling and assistance to enrollees dissatisfied with their treatment by health insurance issuers and group health plans in regard to such coverage or plans and with respect to grievances and appeals regarding determinations under such coverage or plans.

(b) FEDERAL ROLE.—In the case of any State that does not provide for such an Ombudsman under subsection (a), the Secretary shall provide for the creation and operation of a Health Insurance Ombudsman through

a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers and that is responsible for carrying out with respect to that State the functions otherwise provided under subsection (a) by a Health Insurance Ombudsman.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such amounts as may be necessary to provide for grants to States for contracts for Health Insurance Ombudsmen under subsection (a) or contracts for such Ombudsmen under subsection (b).

(d) CONSTRUCTION.—Nothing in this section shall be construed to prevent the use of other forms of enrollee assistance.

Subtitle D—Grievance and Appeals Procedures

SEC. 131. ESTABLISHMENT OF GRIEVANCE PROCESS.

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or

other individuals acting on behalf of an individual and with the individual's consent, regarding any aspect of the plan's or issuer's services.

(2) SCOPE.—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this title.

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

(5) Notification to the continuous quality improvement program under section 111(a) of all grievances and appeals relating to quality of care.

SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT OF APPEAL.—

(1) IN GENERAL.—A participant or beneficiary in a group health plan, and an enrollee in health insurance coverage offered by a health insurance issuer, and any provider or other person acting on behalf of such an individual with the individual's consent, may appeal any appealable decision (as defined in paragraph (2)) under the procedures described in this section and (to the extent applicable) section 133. Such individuals and providers shall be provided with a written explanation of the appeal process and the determination upon the conclusion of the appeals process and as provided in section 121(b)(8).

(2) APPEALABLE DECISION DEFINED.—In this section, the term "appealable decision" means any of the following:

(A) Denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a benefit, including a failure to

cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(B) Failure to provide coverage of emergency services or reimbursement of maintenance care or post-stabilization care under section 101.

(C) Failure to provide a choice of provider under section 103.

(D) Failure to provide qualified health care providers under section 103.

(E) Failure to provide access to specialty and other care under section 104.

(F) Failure to provide continuation of care under section 105.

(G) Failure to provide coverage of routine patient costs in connection with an approval clinical trial under section 106.

(H) Failure to provide access to needed drugs under section 107(a)(3) or 107(b).

(I) Discrimination in delivery of services in violation of section 109.

(J) An adverse determination under a utilization review program under section 115.

(K) The imposition of a limitation that is prohibited under section 151.

(b) INTERNAL APPEAL PROCESS.—

(1) IN GENERAL.—Each group health plan and health insurance issuer shall establish and maintain an internal appeal process under which any participant, beneficiary, or enrollee, or any provider or other person acting on behalf of such an individual with the individual's consent, who is dissatisfied with any appealable decision has the opportunity to appeal the decision through an internal appeal process. The appeal may be communicated orally.

(2) CONDUCT OF REVIEW.—

(A) IN GENERAL.—The process shall include a review of the decision by a physician or other health care professional (or professionals) who has been selected by the plan or issuer and who has not been involved in the appealable decision at issue in the appeal.

(B) AVAILABILITY AND PARTICIPATION OF CLINICAL PEERS.—The individuals conducting such review shall include one or more clinical peers (as defined in section 191(c)(2)) who have not been involved in the appealable decision at issue in the appeal.

(3) DEADLINE.—

(A) IN GENERAL.—Subject to subsection (c), the plan or issuer shall conclude each appeal as soon as possible after the time of the receipt of the appeal in accordance with medical exigencies of the case involved, but in no event later than—

(i) 72 hours after the time of receipt of an expedited appeal, and

(ii) except as provided in subparagraph (B), 30 business days after such time (or, if the participant, beneficiary, or enrollee supplies additional information that was not available to the plan or issuer at the time of the receipt of the appeal, after the date of supplying such additional information) in the case of all other appeals.

(B) EXTENSION.—In the case of an appeal that does not relate to a decision regarding an expedited appeal and that does not involve medical exigencies, if a group health plan or health insurance issuer is unable to conclude the appeal within the time period provided under subparagraph (A)(ii) due to circumstances beyond

the control of the plan or issuer, the deadline shall be extended for up to an additional 10 business days if the plan or issuer provides, on or before 10 days before the deadline otherwise applicable, written notice to the participant, beneficiary, or enrollee and the provider involved of the extension and the reasons for the extension.

(4) NOTICE.—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals under subsection (b) in situations in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee (including in the case of a child, development) or such an individual's ability to regain maximum function.

(2) PROCESS.—Under such procedures—

(A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal;

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the appeal if the request for an expedited appeal is submitted under subparagraph (A) by a physician and the request indicates that the situation described in paragraph (1) exists.

(d) DIRECT USE OF FURTHER APPEALS.—In the event that the plan or issuer fails to comply with any of the deadlines for completion of appeals under this section or in the event that the plan or issuer for any reason expressly waives its rights to an internal review of an appeal under subsection (b), the participant, beneficiary, or enrollee involved and the provider involved shall be relieved of any obligation to complete the appeal involved and may, at such an individual's or provider's option, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—For purposes of this section, the term ''externally appealable decision'' means an appealable decision (as defined in section 132(a)(2)) if—

(A) the amount involved exceeds a significant threshold; or

(B) the patient's life or health is jeopardized (including, in the case of a child, development) as a consequence of the decision.

Such term does not include a denial of coverage for services that are specifically listed in plan or coverage documents as excluded from coverage.

(3) EXHAUSTION OF INTERNAL APPEALS PROCESS.—A plan or issuer may condition the use of an external appeal process in the case of an externally

appealable decision upon completion of the internal review process provided under section 132, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Subject to subparagraph (B), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) RESTRICTIONS ON QUALIFIED EXTERNAL APPEAL ENTITY.—

(i) BY STATE FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in such a manner as to assure an unbiased determination.

(ii) BY FEDERAL GOVERNMENT FOR GROUP HEALTH PLANS.—With respect to group health plans, the appropriate Secretary may exercise the same authority as a State may exercise with respect to health insurance issuers under clause (i). Such authority may include requiring the use of the qualified external appeal entity designated or selected under such clause.

(iii) LIMITATION ON PLAN OR ISSUER SELECTION.—If an applicable authority permits more than one entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

(I) shall assure that the selection process will not create any incentives for external appeal entities to make a decision in a biased manner, and

(II) shall implement procedures for auditing a sample of decisions by such entities to assure that no such

decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that the direct costs of the process (not including costs of representation of a participant, beneficiary, or enrollee) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR PROCESS; DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination.

(B) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine whether a

decision is an externally appealable decision and related decisions, including—

(i) whether such a decision involves an expedited appeal;

(ii) the appropriate deadlines for internal review process required due to medical exigencies in a case; and

(iii) whether such a process has been completed.

(C) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to an externally appealable decision—

(i) may submit and review evidence related to the issues in dispute,

(ii) may use the assistance or representation of one or more individuals (any of whom may be an attorney), and

(iii) may make an oral presentation.

(D) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to all its records relating to the matter of the externally appealable decision and to all provisions of the plan or health insurance cov-

erage (including any coverage manual) relating to the matter.

(E) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be binding on the plan or issuer;

(iii) be made in accordance with the medical exigencies of the case involved, but in no event later than 60 days (or 72 hours in the case of an expedited appeal) from the date of completion of the filing of notice of external appeal of the decision;

(iv) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(v) inform the participant, beneficiary, or enrollee of the individual's rights to seek further review by the courts (or other process) of the external appeal determination.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term "qualified external appeal entity" means, in relation to a plan or issuer, an entity (which may be a governmental entity) that is certified under paragraph (2) as meeting the following requirements:

(A) There is no real or apparent conflict of interest that would impede the entity conducting external appeal activities independent of the plan or issuer.

(B) The entity conducts external appeal activities through clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(3)(E).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1) by the Secretary of Labor (or under a process recognized or approved by the Secretary of Labor); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements by the applicable State authority (or, if the State has not established an adequate certification and recertification process, by the Secretary of Health and Human Services, or under a process recognized or approved by such Secretary).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a specification of—

(i) the information required to be submitted as a condition of recertification on

the entity's performance of external appeal activities, which information shall include the number of cases reviewed, a summary of the disposition of those cases, the length of time in making determinations on those cases, and such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted; and

(ii) the periodicity which recertification will be required.

(d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—Nothing in this title shall be construed as removing any legal rights of participants, beneficiaries, enrollees, and others under State or Federal law, including the right to file judicial actions to enforce rights.

Subtitle E—Protecting the Doctor-Patient Relationship

SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) PROHIBITION.—

(1) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or

health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with the provider's patient.

(2) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of paragraph (1) shall be null and void.

(b) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a group health plan or health insurance issuer to assure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or

scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

(2) to permit a health care provider to misrepresent the scope of benefits covered under the group health plan or health insurance coverage or to otherwise require a group health plan health insurance issuer to reimburse providers for benefits not covered under the plan or coverage.

(c) MEDICAL COMMUNICATION DEFINED.—In this section:

(1) IN GENERAL.—The term "medical communication" means any communication made by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) with respect to—

(A) the patient's health status, medical care, or treatment options;

(B) any utilization review requirements that may affect treatment options for the patient; or

(C) any financial incentives that may affect the treatment of the patient.

(2) MISREPRESENTATION.—The term "medical communication" does not include a communication by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) if the communication involves a knowing or willful misrepresentation by such provider.

SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEMNIFICATION OR IMPROPER INCENTIVE ARRANGEMENTS.

(a) PROHIBITION OF TRANSFER OF INDEMNIFICATION.—

(1) IN GENERAL.—No contract or agreement between a group health plan or health insurance issuer (or any agent acting on behalf of such a plan or issuer) and a health care provider shall contain any provision purporting to transfer to the health care provider by indemnification or otherwise any liability relating to activities, actions, or omissions of the plan, issuer, or agent (as opposed to the provider).

(2) NULLIFICATION.—Any contract or agreement provision described in paragraph (1) shall be null and void.

(b) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

(1) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in subparagraph (A) of such section are met with respect to such a plan.

(2) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION OF HEALTH CARE PROFESSIONALS.

(a) PROCEDURES.—Insofar as a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits through participating health care professionals, the plan or issuer shall establish reasonable procedures relating to the participation (under an agree-

ment between a professional and the plan or issuer) of such professionals under the plan or coverage. Such procedures shall include—

(1) providing notice of the rules regarding participation;

(2) providing written notice of participation decisions that are adverse to professionals; and

(3) providing a process within the plan or issuer for appealing such adverse decisions, including the presentation of information and views of the professional regarding such decision.

(b) CONSULTATION IN MEDICAL POLICIES.—A group health plan, and health insurance issuer that offers health insurance coverage, shall consult with participating physicians (if any) regarding the plan's or issuer's medical policy, quality, and medical management procedures.

SEC. 144. PROTECTION FOR PATIENT ADVOCACY.

(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan, and a health insurance issuer with respect to the provision of health insurance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's, beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including

an internal or external review or appeal process) under this title.

(b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients

within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or

that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

(3) EXCEPTION AND SPECIAL RULE.—

(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term "protected health care professional" means an individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

Subtitle F—Promoting Good Medical Practice

SEC. 151. PROMOTING GOOD MEDICAL PRACTICE.

(a) PROHIBITING ARBITRARY LIMITATIONS OR CONDITIONS FOR THE PROVISION OF SERVICES.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, may not arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting in which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit.

(2) CONSTRUCTION.—Paragraph (1) shall not be construed as prohibiting a plan or issuer from limiting the delivery of services to one or more health care providers within a network of such providers.

(3) MANNER OR SETTING DEFINED.—In paragraph (1), the term "manner or setting" means the location of treatment, such as whether treatment is provided on an inpatient or outpatient basis, and the duration of treatment, such as the number of days in a hospital. Such term does not include the coverage of a particular service or treatment.

(b) NO CHANGE IN COVERAGE.—Subsection (a) shall not be construed as requiring coverage of particular services the coverage of which is otherwise not covered under

the terms of the plan or coverage or from conducting utilization review activities consistent with this subsection.

(c) MEDICAL NECESSITY OR APPROPRIATENESS DEFINED.—In subsection (a), the term "medically necessary or appropriate" means, with respect to a service or benefit, a service or benefit which is consistent with generally accepted principles of professional medical practice.

SEC. 152. STANDARDS RELATING TO BENEFITS FOR CERTAIN BREAST CANCER TREATMENT.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in his or her professional judgment consistent with generally accepted medical standards, in consultation with the patient, to be medically appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

(1) deny to a woman eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;

(2) provide monetary payments or rebates to women to encourage such women to accept less than the minimum protections available under this section;

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section;

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

(5) subject to subsection (c)(3), restrict benefits for any portion of a period within a hospital length of stay required under subsection (a) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(c) RULES OF CONSTRUCTION.—

(1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary—

(A) to undergo a mastectomy or lymph node dissection in a hospital; or

(B) to stay in the hospital for a fixed period of time following a mastectomy or lymph node dissection.

(2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer.

(3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissec-

tion for the treatment of breast cancer under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under subsection (a) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(d) LEVEL AND TYPE OF REIMBURSEMENTS.—Nothing in this section shall be construed to prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating the level and type of reimbursement with a provider for care provided in accordance with this section.

(e) EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1) of the Public Health Service Act) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a mastectomy performed for

treatment of breast cancer and at least a 24-hour hospital length of stay following a lymph node dissection for treatment of breast cancer.

(B) Such State law requires, in connection with such coverage for surgical treatment of breast cancer, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the woman involved.

(2) CONSTRUCTION.—Section 2723(a)(1) of the Public Health Service Act and section 731(a)(1) of the Employee Retirement Income Security Act of 1974 shall not be construed as superseding a State law described in paragraph (1).

Subtitle G—Definitions

SEC. 191. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—The provisions of section 2971 of the Public Health Service Act shall apply for purposes of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term "Secretary" means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the Secretary of the Treasury and the term

"appropriate Secretary" means the Secretary of Health and Human Services in relation to carrying out this title under sections 2707 and 2753 of the Public Health Service Act, the Secretary of Labor in relation to carrying out this title under section 714 of the Employee Retirement Income Security Act of 1974, and the Secretary of the Treasury in relation to carrying out this title under chapter 100 and section 4980D of the Internal Revenue Code of 1986.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) APPLICABLE AUTHORITY.—The term "applicable authority" means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(2) CLINICAL PEER.—The term "clinical peer" means, with respect to a review or appeal, a physician (allopathic or osteopathic) or other health care professional who holds a non-restricted license in a State and who is appropriately credentialed in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment rendered by a physician.

(3) HEALTH CARE PROVIDER.—The term "health care provider" includes a physician or other health care professional, as well as an institutional provider of health care services.

(4) NONPARTICIPATING.—The term "nonparticipating" means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(5) PARTICIPATING.—The term "participating" means, with respect to a health care provider that provides health care items and services to a partici-

pant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2), this title shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this title.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) RULES OF CONSTRUCTION.—Except as provided in section 152, nothing in this title shall be construed as

requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(c) DEFINITIONS.—For purposes of this section:

(1) STATE LAW.—The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term "State" includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

SEC. 193. REGULATIONS.

The Secretaries of Health and Human Services, Labor, and the Treasury shall issue such regulations as may be necessary or appropriate to carry out this title. Such regulations shall be issued consistent with section 104 of Health Insurance Portability and Accountability Act of 1996. Such Secretaries may promulgate any interim final rules as the Secretaries determine are appropriate to carry out this title.

TITLE II—APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER PUBLIC HEALTH SERVICE ACT

SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following new section:

"SEC. 2707. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Each group health plan shall comply with patient protection requirements under title I of the Patients' Bill of Rights Act of 1999, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

"(b) NOTICE.—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with re-

spect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice requirement as if such section applied to such issuer and such issuer were a group health plan.".

(b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting "(other than section 2707)" after "requirements of such subparts".

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Subpart 3 of part B of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following new section:

"SEC. 2753. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Each health insurance issuer shall comply with patient protection requirements under title I of the Patients' Bill of Rights Act of 1999 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

"(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under sec-

tion 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such title as if such section applied to such issuer and such issuer were a group health plan.''.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277), is amended by adding at the end the following:

''SEC. 714. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of title I of the Patients' Bill of Rights Act of 1999 (as in effect as

of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Patients' Bill of Rights Act of 1999 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

"(A) Section 101 (relating to access to emergency care).

"(B) Section 102(a)(1) (relating to offering option to purchase point-of-service coverage), but only insofar as the plan is meeting such requirement through an agreement with the issuer to offer the option to purchase point-of-service coverage under such section.

"(C) Section 103 (relating to choice of providers).

"(D) Section 104 (relating to access to specialty care).

"(E) Section 105(a)(1) (relating to continuity in case of termination of provider contract) and section 105(a)(2) (relating to continuity in case of termination of issuer contract), but only insofar as a replacement issuer assumes the obligation for continuity of care.

"(F) Section 106 (relating to coverage for individuals participating in approved clinical trials.)

"(G) Section 107 (relating to access to needed prescription drugs).

"(H) Section 108 (relating to adequacy of provider network).

"(I) Subtitle B (relating to quality assurance).

"(J) Section 143 (relating to additional rules regarding participation of health care professionals).

"(K) Section 152 (relating to standards relating to benefits for certain breast cancer treatment).

"(2) INFORMATION.—With respect to information required to be provided or made available under section 121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

"(3) GRIEVANCE AND INTERNAL APPEALS.—With respect to the grievance system and internal appeals process required to be established under sections 131 and 132, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process), if the issuer is obligated to provide for (and provides for) such system and process.

"(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 133, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

"(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:

"(A) Section 109 (relating to nondiscrimination in delivery of services).

"(B) Section 141 (relating to prohibition of interference with certain medical communications).

"(C) Section 142 (relating to prohibition against transfer of indemnification or improper incentive arrangements).

"(D) Section 144 (relating to prohibition on retaliation).

"(E) Section 151 (relating to promoting good medical practice).

"(6) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(7) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 144(b)(1) of the Patients' Bill of Rights Act of 1999, for purposes of this subtitle the term 'group health plan' is deemed to include a reference to an institutional health care provider.

"(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

"(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 144(b)(1) of the Patients' Bill of Rights Act of 1999 may file with the Secretary a complaint within 180 days of the date of the alleged retaliation or discrimination.

"(2) INVESTIGATION.—The Secretary shall investigate such complaints and shall determine if a violation of such section has occurred and, if so, shall issue an order to ensure that the protected

health care professional does not suffer any loss of position, pay, or benefits in relation to the plan, issuer, or provider involved, as a result of the violation found by the Secretary.

"(d) CONFORMING REGULATIONS.—The Secretary may issue regulations to coordinate the requirements on group health plans under this section with the requirements imposed under the other provisions of this title.".

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended by inserting "(a)" after "SEC. 503." and by adding at the end the following new subsection:

"(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle D (and section 115) of title I of the Patients' Bill of Rights Act of 1999 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.".

(c) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185(a)) is amended by striking "section 711" and inserting "sections 711 and 714".

(2) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105–277), is amended by inserting after the item relating to section 713 the following new item:

"Sec. 714. Patient protection standards.".

(3) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by inserting "(other than section 144(b))" after "part 7".

SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS INVOLVING HEALTH INSURANCE POLICYHOLDERS.

(a) IN GENERAL.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended by adding at the end the following subsection:

"(e) PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS ARISING OUT OF PROVISION OF HEALTH BENEFITS.—

"(1) IN GENERAL.—Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action brought by a plan participant or beneficiary (or the estate of a plan participant or beneficiary) under

State law to recover damages resulting from personal injury or for wrongful death against any person—

"(A) in connection with the provision of insurance, administrative services, or medical services by such person to or for a group health plan (as defined in section 733), or

"(B) that arises out of the arrangement by such person for the provision of such insurance, administrative services, or medical services by other persons.

"(2) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

"(A) IN GENERAL.—Subject to subparagraph (B), paragraph (1) does not authorize—

"(i) any cause of action against an employer or other plan sponsor maintaining the group health plan or against an employee of such an employer or sponsor acting within the scope of employment, or

"(ii) a right of recovery or indemnity by a person against an employer or other plan sponsor (or such an employee) for damages assessed against the person pur-

suant to a cause of action under paragraph (1).

"(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment) if—

"(i) such action is based on the employer's or other plan sponsor's (or employee's) exercise of discretionary authority to make a decision on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

"(ii) the exercise by such employer or other plan sponsor (or employee of such authority) resulted in personal injury or wrongful death.

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed as permitting a cause of action under State law for the failure to provide an item or service which is not covered under the group health plan involved.

"(4) PERSONAL INJURY DEFINED.—For purposes of this subsection, the term 'personal injury'

means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to acts and omissions occurring on or after the date of the enactment of this Act from which a cause of action arises.

TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986

SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 (as amended by section 1531(a) of the Taxpayer Relief Act of 1997) is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

"Sec. 9813. Standard relating to patient freedom of choice."; and

(2) by inserting after section 9812 the following:

"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

"A group health plan shall comply with the requirements of title I of the Patients' Bill of Rights Act of 1999 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.".

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

SEC. 501. EFFECTIVE DATES AND RELATED RULES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by sections 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2000 (in this section referred to as the "general effective date").

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by sec-

tions 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section 202 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

(c) TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.—

(1) IN GENERAL.—Nothing in this Act (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers offering health insurance coverage, to include as providers religious nonmedical providers;

(B) require such plans or issuers to—

(i) utilize medically based eligibility standards or criteria in deciding provider status of religious nonmedical providers;

(ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;

(iii) utilize medical professionals or criteria in making decisions in internal or external appeals regarding coverage for care by religious nonmedical providers; or

(iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or

(C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the reli-

gious nonmedical treatment or nursing care provided by the provider.

(2) RELIGIOUS NONMEDICAL PROVIDER.—For purposes of this subsection, the term "religious nonmedical provider" means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

SEC. 502. COORDINATION IN IMPLEMENTATION.

Section 104(1) of Health Insurance Portability and Accountability Act of 1996 is amended by striking "this subtitle (and the amendments made by this subtitle and section 401)" and inserting "the provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, the provisions of parts A and C of title XXVII of the Public Health Service Act, chapter 100 of the Internal Revenue Code of 1986, and title I of the Patients' Bill of Rights Act of 1999".

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